

Appl. No. 10/079,605  
Response dated April 5, 2004  
Reply to Office Action of October 3, 2003

## REMARKS

### Comments

In the previous Office Action, claims 1-3, 5, 6, 11, 13-16, 18-21 27-31 were rejected and claims 4, 7-10, 12, 17, 22-26 were withdrawn for consideration. Accordingly, claims 1-31 are currently pending.

### Double Patenting

The Office Action provisionally rejected claims 1-3, 5, 6, 11, 13-16, 18-21, and 27-31 under judicial double patenting over claims in a co-pending application. Applicant disagrees. However, in order to expedite prosecution of this case, applicant submits a terminal disclaimer herewith. Accordingly, applicant believes that claims 28 and 29 are now in condition for allowance.

### 35 USC §102

The Office Action rejected claims 1, 2, 5, 11, 13, 18-21, 27, 30, and 31 under 35 U.S.C. 102(b) as being anticipated by Colley (4,319,580), applicant disagrees.

### Claim 1:

Colley teaches a transducer (52) comprising a conducting layer (78), which the Office Action asserts to be an equivalent to the hollow conducting member. (Column 8, lines 32-39) The conducting layer that Colley teaches cannot be separated from the transducer without destroying the transducer. In claim 1 the transducer and the hollow conducting member are separate elements of the greater medical device. It is improper for the Office Action to equate the conducting layer 78 of Colley with a discrete hollow conducting member. Doing so ignores the fact that the transducer of Colley is not complete without the conducting layer 78. Because Colley does not teach that the conducting layer 78 can exist separately from the transducer, Colley cannot anticipate claim 1.

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Claim 30:

Claim 30 requires directing means for directing the source signal and reflected signal, where the means is in acoustical communication with the transducer assembly. Colley expressly teaches away from this requirement of claim 30. Applicant notes that omni-directional capability (col. 9, lines 31-62) is an undirected means of signal transmission as signal travels in all directions. The teaching of omni-directional capability appears to be the opposite of a directed means of acoustical communication. Applicant is also unable to find any teaching in Colley regarding any member in acoustical communication with transducer. Thus, it is clear that Colley does not teach or suggest the elements of claim 30. Therefore, Colley fails to anticipate claim 30.

Claim 31:

Claim 31 requires a hollow conductive member located at the distal end of the elongate member in conjunction with a transducer, with an acoustically transmitting material distal to the transducer, the hollow conductive member fixed and at least partially circumferentially disposed about a portion of the acoustically transmitting material. Applicant is unable to find any teaching in Colley regarding this configuration.

Claim 31 also requires the hollow conductive member to be fixed at the distal end of the elongate member. In Colley the hollow conductive member (member 56) does not have this requirement. The only preference for the hollow conductive member in Colley is that member 56 is slipped over portion 54B (Column 9, lines 1) of the elongate member 54. Colley shows no teaching that portion 54B is required to be at the distal, proximal, or central part of the elongate member 54. Thus, because there is no location requirement for the hollow conductive member in Colley, claim 31 is not anticipated by it.

It is well established that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in the cited

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reference. The Office Action fails to provide any support, in Colley, for any hollow conductive member and transducer as required by applicant's claim 1. The Office Action fails to provide any support, in Colley, for any member in acoustical communication with transducer for directing means for directing the source signal and reflected signal, as required by applicant's claim 30. The Office Action fails to provide any support, in Colley, for the configuration as required by applicant's claim 31.

Applicant also disagrees that the cited reference anticipates any claim ultimately dependent from either claim 1, 30 or 31, but because of the deficiencies with regards to these latter claims applicant reserves the right to argue each individual rejection of claims 2-3, 5, 6, 11, 13-16, 18-21, and 27-29, if needed at a later time. Applicant requests further clarification to support the rejection, or, in the alternative request that withdrawal of this rejection.

### 35 U.S.C. §103

The Office Action rejected claims 1, 11, 13-15, 18-21, and 30 under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (US 5,316, 001) in view of Webster, Jr. (US 5,916,158). Applicant disagrees.

#### Claim 1:

The Office Action rejected claim 1 as being unpatentable over Ferek-Petric et al (5,316,001) in view of Webster, Jr. (5,916,158), applicant disagrees.

The Office Action fails to establish a proper *prima facie* case of obviousness. A proper *prima facie* case requires that the combination teach or suggest all of the claim elements. Ferek-Petric fails to teach or suggest a hollow conductive member as required by claim 1. The addition of Webster, Jr. adds no hollow conductive member. Instead, Webster teaches an electrode cup which is filled in with a shaped margin to form a smooth continuous surface with the outer surface of the catheter tip (col 7, lines 43-51 & figs 33, 40).

A proper *prima facie* of obviousness also requires a suggestion or motivation of the combination. The office action cites no teaching, suggestion, or

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motivation to make the conducting member hollow. The office action cites that it is well known in the art to provide an alternative hollow conducting electrode, but demonstrates no objective reason as to why such a combination is desirable. A statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the claimed invention was made' " because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). (MPEP 2143.01)

Claims 1 & 30:

Furthermore, it is well understood that if the proposed combination renders the prior art unsatisfactory for its intended purpose, then a proper *prima facie* case of obviousness is not established. Ferik-Petric invention provides a pacemaker comprising sensors for rate responsive ventricular pacing (column 6, lines 1-3). As such, it requires a fixed distance between the tip and the transducer, such that during normal use the transducer is positioned near to and proximal to the tricuspid valve (column 9, lines 50-56). This distance is defined by the anatomical structure of the heart and is shown to be substantial in figure 1, where in normal use the pacing electrode 724 is located at the apex of the right ventricle and the flow measurement assembly 726 (transducer) is located at the area of the tricuspid valve 725. (Figure 1 and Column 7, lines 50-56)

Claims 1 and 30 of applicant's invention requires that the transducer is located towards the distal portion of the elongate member. Any modification of the Ferik-Petric Device to meet the requirements of the application claims 1 or 30 would be counter to the express teachings of Ferik-Petric. The required layout of applicant's invention would render the Ferik-Petric invention unsatisfactory for its intended use by placing the transducer towards the tip of the device. Placing the

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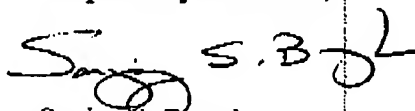
transducer towards the tip eliminates the required gap that the Ferik-Petric teaches.

At the very least, based on the above, applicant believes that the Office Action fails to establish a proper *Prima Facie* case and that the claims in the subject application are patentable over Ferik-Petric in view of Webster, Jr., and that this rejection should be withdrawn.

### SUMMARY

Applicant believes all outstanding issue raised in the previous Office Action are addressed herein and that the claims are in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, a telephone call to the undersigned at (650) 428-1600 will be appreciated.

Respectfully submitted,



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